

Application Serial No. 10/047,578
Filed October 26, 2001
Request for Continued Examination dated July 24, 2006
Atty. Docket: PEDI-04 (formerly KIEL-02)

Listing of Claims

1. (Presently Amended) A composition comprising:

 a plurality of active pharmaceutical ingredients consisting essentially of phenylephrine and pyrilamine, the composition formed from a method comprising:

 forming a solution by dissolving the salt or free base of said active pharmaceutical ingredients in a solvent;

 forming a dispersion by mixing a dispersing agent and tannic acid in a solvent;

 combining the solution and the dispersion, to form tannate salts of the active pharmaceutical ingredients; and

 combining the tannate salts without isolation or purification with at least one suspending agent to produce a homogeneous suspension including pharmaceutically active tannate salts, the homogeneous suspension being in an amount including a plurality of dosage units, the homogeneous suspension being homogeneous in amounts of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units.

2. (Original) The composition of claim 1 wherein the active pharmaceutical ingredients are present in a range of about 0.05% to about 25.0% by weight.

Application Serial No. 10/047,578
Filed October 26, 2001
Request for Continued Examination dated July 24, 2006
Atty. Docket: PEDI-04 (formerly KIEL-02)

3. (Previously Amended) The composition of claim 1 wherein the active pharmaceutical ingredients are selected from the group of salts consisting of maleate, citrate, chloride, bromide, acetate, and sulfate, and combinations thereof.
4. (Original) The composition of claim 1 wherein the tannic acid is natural or synthetic.
5. (Previously Amended) The composition of claim 1 wherein the dispersing agent is selected from the group consisting of magnesium aluminum silicate, xanthan gum and cellulose compounds, and combinations thereof.
6. (Original) The composition of claim 5 wherein the dispersing agent is magnesium aluminum silicate and is present in a range of about 0.05% to about 5.0% by weight.
7. (Original) The composition of claim 1 wherein the tannic acid is present in a range of about 0.05 to about 10.0% by weight.
8. (Original) The composition of claim 6 wherein the magnesium aluminum silicate and tannic acid are present by weight in a ratio in the range of 0.1:1 to 100:1.

Application Serial No. 10/047,578
Filed October 26, 2001
Request for Continued Examination dated July 24, 2006
Atty. Docket: PEDI-04 (formerly KIEL-02)

9. (Original) The composition of claim 1 wherein the tannic acid and the active pharmaceutical ingredients are present by weight in a ratio in the range of 2:1 to 10:1.

10. (Original) The composition of claim 1 wherein the thickening agent is magnesium aluminum silicate and is present in a range of about 0.5% to about 10.0% by weight.

11. (Original) The composition of claim 1 wherein the suspending agent is kaolin and is present in a range of about 0.5 to about 10.0% by weight.

12. (Original) The composition of claim 1 wherein the sweetening agents include sucrose present in a range of about 5.0% to about 50.0% by weight, and saccharin sodium present in a range of about 0.01% to about 3.0% by weight.

13. (Original) The composition of claim 1 wherein the flavoring agent is artificial grape and is present in a range of about 0.01% to about 2.0% by weight.

14. (Original) The composition of claim 1 wherein the second solvent is water and is present in a range of about 10.0 to about 75.0% by weight.

Application Serial No. 10/047,578
Filed October 26, 2001
Request for Continued Examination dated July 24, 2006
Atty. Docket: PEDI-04 (formerly KIEL-02)

15. (Original) The composition of claim 1 wherein said second solvent is glycerin and is present in a range of about 2.5% to about 20.0% by weight.

16. (Original) The composition of claim 1 wherein the preservative is methylparaben and is present in a range of about 0.01 to about 1.0% by weight.

17. (Original) The composition of claim 1 wherein the pH adjusting agent is benzoic acid and is present in a range of about 0.05 to about 1.0% by weight.

18. (Original) The composition of claim 1 wherein the anti-caking agent is pectin and is present in the range of about 0.5 to about 10.0% by weight.

19. (Original) The composition of claim 1 wherein the pH of said liquid dosage form is in a range of about 3.5 to 6.5.

20. (Original) The composition of claim 1 wherein the pharmaceutically active tannate salts are pyrilamine tannate present at about 30mg and phenylephrine tannate present at about 12.5mg.

Application Serial No. 10/047,578
Filed October 26, 2001
Request for Continued Examination dated July 24, 2006
Atty. Docket: PEDI-04 (formerly KIEL-02)

21. (Original) The composition of claim 19 wherein said liquid dosage form is a suspension.

22. (Previously Canceled)

23. (Previously Canceled)

24. (Previously Canceled)

25. (Previously Canceled)

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30. (Previously Canceled)

Application Serial No. 10/047,578
Filed October 26, 2001
Request for Continued Examination dated July 24, 2006
Atty. Docket: PEDI-04 (formerly KIEL-02)

31. (Presently Amended) A composition comprising:

 a plurality of active pharmaceutical ingredients consisting essentially of phenylephrine and pyrilamine, the composition formed from a method comprising:

 forming a solution by dissolving the salt or free base of said active pharmaceutical ingredients in a solvent;

 forming a powder mixture by mixing a dispersing agent, diluent and tannic acid;

 combining the solution and the powder mixture to form tannate salts of the active pharmaceutical ingredients; and

 combining the tannate salts without isolation or purification with at least one tablet excipient to prepare a homogeneous granulation including pharmaceutically active tannate salts, the homogeneous granulation being in an amount to include a plurality of dosage units, the homogeneous granulation being homogeneous in amounts of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units.

32. (Previously Amended) The composition of claim 31 wherein the active pharmaceutical ingredients are free bases or salts selected from the group consisting of maleate, citrate, chloride, hydrochloride, bromide, hydrobromide, acetate, sulfate, mesylate, palmitate, and stearate, and combinations thereof.

Application Serial No. 10/047,578
Filed October 26, 2001
Request for Continued Examination dated July 24, 2006
Atty. Docket: PEDI-04 (formerly KIEL-02)

33. (Previously Amended) The composition of claim 31 wherein the tannic acid is natural or synthetic.

34. (Previously Amended) The composition of claim 31 wherein the dispersing agent is selected from the group consisting of magnesium aluminum silicate, xanthan gum and cellulose compounds, and combinations thereof.

35. (Previously Amended) The composition of claim 31 wherein the solvents are selected from the group consisting of purified water, ethanol, diethylether, methylene chloride, acetone, and isopropyl alcohol, and combinations thereof.

36. (Previously Amended) The composition of claim 31 wherein the diluent is selected from the group consisting of lactose, microcrystalline cellulose, sucrose and mannitol, and combinations thereof, and is present in a concentration of about 1.0 to about 75.0%.

37. (Previously Amended) The composition of claim 31 wherein the binder solution comprises material selected from the group consisting of corn starch, pregelatinized starch, potato starch, polyvinylpyrrolidone and xanthan gum, and combinations thereof, and is present in a concentration of about 0.1% to about 20.0%.

Application Serial No. 10/047,578
Filed October 26, 2001
Request for Continued Examination dated July 24, 2006
Atty. Docket: PEDI-04 (formerly KIEL-02)

38. (Previously Amended) The composition of claim 37 wherein the binder solution further comprises a solvent.

39. (Previously Amended) The composition of claim 38 wherein the solvent is selected from the group consisting of purified water, ethanol, diethylether, methylene chloride, acetone, and isopropyl alcohol, and combinations thereof.

40. (Previously Amended) The composition of claim 31 wherein the dry binding/matrix forming agents are selected from the group consisting of methylcellulose, hydroxypropyl methyl cellulose, ethylcellulose, hydroxypropyl cellulose, xanthan gum and polyvinyl pyrrolidone, and combinations thereof, and each is present at a concentration of about 0.1% to about 20.0%.

41. (Previously Amended) The composition of claim 31 wherein the coloring agents are selected from the group consisting of blue, red, yellow, green, orange, and purple, and combinations thereof, and each is present at a concentration of about 0.01% to about 2.0%.

42. (Previously Amended) The composition of claim 31 wherein the sweetening agents are selected from the group consisting of sucrose, saccharin sodium, xylitol and

Application Serial No. 10/047,578
Filed October 26, 2001
Request for Continued Examination dated July 24, 2006
Atty. Docket: PEDI-04 (formerly KIEL-02)

sucralose, and combinations thereof, and each is present at a concentration of about 0.01% to about 40.0%.

43. (Previously Amended) The composition of claim 31 wherein the flavoring agents are selected from grape, cherry, orange, lime and strawberry, and combinations thereof, and is present in a concentration of about 0.01% to about 3.0%.

44. (Previously Amended) The composition of claim 31 wherein the dispersing agent is magnesium aluminum silicate and is present in about 0.05% to about 15.0% by weight.

45. (Previously Amended) The composition of claim 31 wherein the tannic acid is present in the range of about 0.05% to about 30.0% by weight.

46. (Previously Amended) The composition of claim 44 wherein the ratio of magnesium aluminum silicate to tannic acid is present in the weight ratio of 0.1:1 to 100:1.

47. (Previously Amended) The composition of claim 31 wherein the tannic acid and the active pharmaceutical ingredients are present in the weight ratio 2:1 to 10:1.

Application Serial No. 10/047,578
Filed October 26, 2001
Request for Continued Examination dated July 24, 2006
Atty. Docket: PEDI-04 (formerly KIEL-02)

48. (Previously Amended) The composition of claim 31 wherein the tannate salts are pyrilamine tannate present at 30mg and phenylephrine tannate present at 25mg.

49. (Previously Canceled)

50. (Previously Canceled)

51. (Previously Canceled)

52. (Previously Canceled)

Application Serial No. 10/047,578
Filed October 26, 2001
Request for Continued Examination dated July 24, 2006
Atty. Docket: PEDI-04 (formerly KIEL-02)

53. (Presently Amended) A homogeneous composition comprising:

a plurality of active pharmaceutical ingredients comprising tannate salts,
the homogeneous composition being in an amount to include a plurality of dosage units,
the homogeneous composition being homogeneous in amounts of active
pharmaceutical ingredients in each of the dosage units when compared with each of the
other dosage units, the homogeneous composition being formed by a method
comprising:

dissolving the salt or free base of active pharmaceutical ingredients
consisting essentially of phenylephrine and pyrilamine in a solvent to form a solution;

mixing a dispersing agent and tannic acid in a solvent to form a
dispersion; and

transferring at least a portion of the solution to the dispersion, to form
tannate salts of the active pharmaceutical ingredients without isolation or purification.